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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,027	05/14/2001	Bernhard Hering	1432.05US02	7980

24113 7590 02/26/2004

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EXAMINER

BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

107

Office Action Summary**Application No.**

09/855,027

Applicant(s)

HERING ET AL.

Examiner

Michail A Belyavskyi

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-42, 66-67 and 69 - 79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-42, 66-67 and 69 - 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/03 has been entered.

Claims 40-42, 65-67 and 69 – 79 are pending.

Claims 40-42, 65-67 and 69 – 79 drawn to a method of inducing mixed chimerism in a recipient of pancreatic islet cell transplantation are under consideration in the instant application.

2. Claims 40-42, 66-67 and 69 – 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,558,662 in view of US Patent NO: 6,447,765

US Patent '662 teaches a method of inducing mixed chemirism in a recipient of allogenic or xenogenic donor tissue, comprising administering a conditional myeloreductive non-myeloablative treatment to the recipient and performing a donor bone marrow cell transplantation (see entire document, Abstract, columns 5, 10 , 11 and claim 1 in particular). US Patent '662 teaches that administering a conditional myeloreductive non-myeloablative treatment to the recipient and performing a donor bone marrow cell transplantation will reduce GVHD associated with mismatched allogenic or xenogenic donor tissue, yet providing significant graft-versus leukemia effect and the like (see column 1 in particular). US Patent '662 teaches several treatment conditional protocols, including treatment with fludarabine phosphate and mitoxantrone or cisplatin (see column 10, lines 40-56 in particular). US Patent '662 teaches administering the immune blockade treatment including treatment with CTLA4 (see column 11, lines 15-35 in particular). US Patent '662 teaches conditional treatment includes low dose irradiation (see colums 5 and 13 in particular). US Patent '662 teaches that conditional treatment includes treating the subject prior to the bone marrow cell transplant (see columns 11 and 12 in particular). US Patent '662 teaches that bone marrow cells includes administering stem cells in at least two doses over a time course (see column 15 in particular).

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US Patent '662 does not explicitly teach a method of inducing a mixed chimerism in a recipient of pancreatic islet cell transplant, wherein a donor bone marrow transplant is performed within 96 or 48 or 12 hours before or after the pancreatic islet cell transplant.

US Patent '765 teaches a method of transplanting a donor tissue, the method comprising the step of administering a bone marrow cell transplant from a donor to a recipient (see entire document, Abstract in particular). US Patent '765 also teaches using an immunosuppressive treatment of the recipient (see column 1, line 60-65 in particular). US Patent '765 teaches that treating the patients and bone marrow cell transplant are done within period of time ranging from 4 to 72 hours.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '765 to US Patent '662 to obtain a method of inducing a mixed chimerism in a recipient of pancreatic islet cell transplant, wherein a donor bone marrow transplant is performed within 96 or 48 or 12 hours before or after the pancreatic islet cell transplant. It is clear that both the prior art and applicant administer the same treatment to the same patients to achieve the same results. Pancreatic islet cell transplant is a donor tissue transplant. Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to conclude that a method of inducing mixed chimerism in a recipient of donor tissue transplant, comprising administering a conditional myeloreductive non-myeloablative treatment taught by US Patent '662 would obviously induce a mixed chimerism in a recipient of pancreatic islet cell transplant. When the prior art method is the same as a method described in the specification, it can be assumed the method will obviously perform the claimed process absent a showing of unobvious property. Moreover, it would be conventional and within the skill of the art to determine the optimum timing wherein a donor bone marrow transplant is performed. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Semaker*, 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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3. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,558,662 in view of US Patent NO: 6,447,765 as applied to claims 40-42, 66-67, 69 – 79 above, and further in view of Lynt et al. (Transplantation, 1997, 63, 6, 910-911).

The teaching of US Patent '662 and Patent '765 have been discussed supra.

The combined references does not teaches that a donor is a clinical cadaver.

Lynt et al. teach a method of transplanting a donor tissue from brain-dead organ donor (clinical cadaver) (see entire document, Abstract in particular). Lynt et al. also teach that using cadaveric donors for organ transplantation would be beneficial and of great importance and would provide organ transplantation to those who would have previously been refuses for transplantation (see Abstract in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Lynt et al., to those of US Patent '662 and Patent '765 to obtain a claimed method of transplanting a donor tissues, wherein the donor is a clinical cadaver.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because using cadaveric donors for organ transplantation would be beneficial and of great importance and would provide organ transplantation to those who would have previously been refuses for transplantation as taught by Lynt et al. and can be used for bone marrow cell transplant from a donor to recipient as taught by US Patent '662 and Patent '765.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
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February 23, 2004


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